

PCT

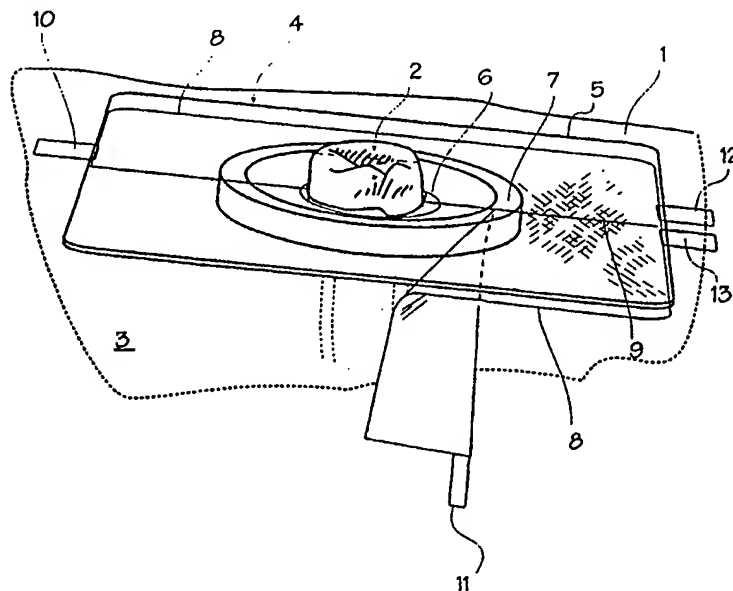
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61F 13/00	A1	(11) International Publication Number: WO 00/44324 (43) International Publication Date: 3 August 2000 (03.08.00)
(21) International Application Number: PCT/US00/02556 (22) International Filing Date: 31 January 2000 (31.01.00) (30) Priority Data: 09/241,791 1 February 1999 (01.02.99) US (71)(72) Applicant and Inventor: WAGNER, Neldon, C. [US/US]; 19615 S.W. Cascadia Street, Aloha, OR 97007 (US). (74) Agent: CROCKETT, K., David; Crockett & Crockett, 22362 Rosebriar, Mission Viejo, CA 92962 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: **ADHESIVE PAD WITH FLEXIBLE RELEASE PAPER**



(57) Abstract

This invention is a release paper (8) formulated for sufficient flexibility to be peeled out from under an adhesive appliance (100) to be applied to the body (such as an ostomy face plate), while the adhesive device is held in place on the body.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

Adhesive Pad with Flexible Release PaperField of the Inventions

The inventions described below relate to the field of medical bandages, adhesives dressings, wound dressings and
5 ostomy appliances.

Background of the Inventions

Numerous adhesive patches are used to apply things to the body in treating a wide variety of conditions. Ostomy appliances are pouches, mounting rings, and faceplates, held
10 to the body with a ring of adhesive material surrounding the stoma. Adhesive bandages such as Band-Aids use a border of adhesive tape over a sterile bandage to tape the bandage in place over a wound. Pressure sensitive adhesive wound dressings consist of a sheet of hydrogel which adheres
15 directly to burns and wounds. Each of these devices require that the adhesive surface be covered with a release paper during storage and handling. The release paper protects the adhesive from sticking to packaging and from collecting dirt and debris, and thereby losing both its sterile and adhesive
20 qualities.

Many of these devices are intended to be applied by the patient who requires them. However, they are not easy to apply: once the release paper is removed, the exposed tape prematurely sticks to the body whenever it is inadvertently
25 touched to the skin, or sticks to itself if the adhesive surface folds over onto itself. If the patient does not get the placement just right the first time, he has to peel it off and try again, thus degrading the adhesive and perhaps hampering the medical effectiveness of the device.

In one area of interest, the flexible release paper is used with an ostomy faceplate. An ostomy face plate with a mounting ring is adhered to the body with an adhesive in the form of a square sheet or round sheet with a central hole which accommodates the stoma. The adhesive pad fits directly over the stoma in some versions of the ostomy face plate which have a pouch mounting ring formed integrally into the adhesive pad, and over the mounting ring in other designs. (A pouch is connected to the mounting ring.) The adhesive pad is referred to as an adhesive disk, a wafer, or a bandage by some manufactures. In existing adhesive pads, the sticky side is protected with a siliconized "release paper" that is removed prior to application. Usually two small strips of release paper are left on opposite sides to handle the device during application (as in the Sur-Fit™ wafers). The strips are removed after everything is in place and secured. In another commercially available system, the pouch and faceplate are provided in a single piece, and the pouch, faceplate and adhesive disk are applied all at the same time.

20

Summary

In the devices described below, the ostomy face plate and adhesive pad system are improved. The original release paper is replaced with a silicone impregnated cloth that is sheer, flexible, and tear resistant. It is shaped like a closed "C" (or broken "O") that covers the same area as the original release paper. To initiate removal, the new "release cloth" has one or more starter tabs (at the broken part of the perimeter) that extend beyond the adhesives' boundary.

With adhesive pads of my current composition or of the currently widespread composition of tapes or skin barrier compounds, the application of the adhesive pad is now simplified: The "release cloth" remains attached to the

adhesive pad while applying the adhesive pad over the stoma. Thus, no sticky adhesive surfaces are exposed while the adhesive pad is maneuvered into place. The patient applying the adhesive pad may slide the adhesive pad around and
5 position it as necessary, holding it flat against the skin as if it were permanently in place. When satisfied with the adhesive pad's position, the patient can peel the release cloth from under the adhesive pad, peeling out the release cloth by pulling on the accessible 'starter tabs' formed on
10 the outer edge of the adhesive pad and progressively pulling the release paper around the perimeter of the adhesive pad. As the cloth peels out, the exposed tape will immediately adhere to the skin, resulting in a convenient and superior positioning. In another embodiment, the starter tabs are
15 connected to the release paper at a point near the planar center, away from the outer edge of the release paper, and these release tabs extend underneath the release paper so that they are accessible for pulling while the adhesive pad is held close to the body. Since the objective is to peel away the
20 release cloth without disturbing the position of the adhesive pad, the release cloth should be sheer and flexible, which will result in minimum drag and low profile when the cloth slightly folds back on itself while being peeled out.

While the device is described below in relation to the
25 adhesive pad used with ostomy faceplates, it may be adapted to be used with any sort of adhesive device applied to the body.

Brief Description of the Drawings

Figures 1, 2 and 3 illustrate and exemplary use of the release paper in an ostomy face plate.

30 Figure 4 illustrates an embodiment of the release paper.

Figure 5 illustrates an embodiment of the release paper.

Figure 6 illustrates an embodiment of the release paper with underfold pull tabs.

Figure 7 illustrates several embodiments of pull tabs in a release paper.

5 Figure 8 illustrates a wound dressing with flexible release paper.

Detailed Description of the Inventions

An ostomy faceplate with an adhesive wafer is used to illustrate the application of the release paper. An ostomy is
10 required in a patient when some disease or injury make normal digestion and waste through the large and small intestines impossible. The patient's small intestine is severed at the ileum, and the ileum is inserted in a hole in the abdomen 1, then cuffed and sutured in place to form a stoma 2. The stoma
15 allows discharge of waste from the small intestine into a pouch which the patient attaches to the stoma and carries continuously. The stoma 2 is surrounded by normal abdominal skin, referred to as the peristomal skin and marked as item 3. To provide a neat and leakproof connection between the pouch
20 and the stoma, a faceplate 4 is installed over the stoma, and comprises an adhesive pad 5 with a stoma opening 6 near the center of the pad, and with a pouch coupling ring 7 which is integrally formed with the faceplate. The faceplate is mounted on the abdomen 1 and secured to the skin through the
25 adhesion of the pressure sensitive adhesive backing of the adhesive pad. The adhesives typically used have very high tack.

The faceplate 4 is backed with a release paper 8. The release paper covers the anterior surface of the faceplate
30 (the surface that faces the body). The release paper is pre-cut or pre-scored along line 9. The pull tabs 10, 11, 12 and

13 are easy to grab and pull with the fingers. The release paper is very flexible, but is preferably strong enough that it will not tear during removal. In use, the patient places the ostomy face plate 4 on the abdomen and over the stoma 2 in the desired position. While holding the faceplate in position with one hand, the patient can grasp a pull tab and pull it out outwardly, drawing the release paper from under the adhesive pad by folding it under itself, between the adhesive pad and the abdomen. As shown in Figure 2, the process has been started, and the release paper has folded under itself and is easily peeled from the adhesive pad. Figure 3 illustrates the process with the release paper more fully everted under the adhesive pad. Figures 2 and 3 illustrate the release paper being removed by twisting starter tab number 11 one half turn upon initiation. This causes a single fold in the release paper upon removal. An alternative technique is to simply pull the starter tab through the trajectory just described, without twisting the tab. When being pulled out, the release material will either form an "S" shape at the point of separation or bunch up in a non specific configuration, but because of the sheerness and flexibility of the material, successful removal of the release paper occurs. There is no need to lift the adhesive pad away from the body, and out of alignment with the intended placement over the site of the stoma, to remove the release paper. The adhesive pad remains in a substantially planar configuration during placement.

Figure 4 illustrates one form for the release paper 8 intended for use with a stoma face plate and its associated adhesive wafer. The release paper is sized and shaped to substantially cover the adhesive pad with which it is used, and may slightly exceed or fall short of the size of the adhesive pad. The release pad for use with a stoma faceplate has a stoma opening 6 which accommodates the stoma (this

opening may be cut during manufacture at the factory, or it may be cut by the patient when the stoma opening is cut to size just prior to application), and scored or cut along at lines 14 and 15. One or more pull tabs 16 are formed

5 integrally with the release paper and extend substantially beyond the boundary of the adhesive pad so that they can be easily grasped with the fingers. The cut line extends from the outer edge of the release paper to the central opening. As shown in Figure 5, a single cut line may be used, in which

10 case the paper must be everted and peeled from under the adhesive pad in a circular motion. The bridge of uncut release paper 17 in Figure 5 connects the left and right sides of the release paper and ensures that removal of one side of the release paper can be accomplished by continued tension on

15 the prior removed side.

As shown in Figure 6, the pull tab may be formed on the release paper so that they extend under the release paper, and are pulled outwardly from the point of attachment. This more easily initiates the underfolding or everting action which

20 allows the peeling process to take place with the pad in place. Thus, with the pull tabs 21 connected to the release paper 8 at an interior portion of the cut line 22 and being routed under the release paper and between the release paper and the abdomen, when the pull tab is pulled outwardly in the

25 direction of arrow 23, the everting action commences without need for a twisting action by the patient. Figure 7 illustrates several other versions of the release paper with pull tabs connected to interior portions of the release paper yet extended outwardly from under the release paper so that

30 they may be grasped by the user while the adhesive pad is held in place against the abdomen. The release paper 24 of Figure 7 has a plurality of pre-scored or pre-cut lines 25 which define four quarters of release paper surrounding the stoma opening 6. In the first segment 26, the pull tab 27 is

connected to the release paper near the edge of the stoma opening (it need not be exactly at the edge, leaving some room for trimming by the patient). In the second segment 28, the pull tab 29 is connected to the release paper near the edge of the stoma opening, and the width of the pull tab at the line of attachment to the release paper is substantially the same as the width of the release paper segment at the point of attachment. In the third segment 30 the pull tab 31 is connected to the release paper near an interior edge 32 of the precut line defining the segment. In the fourth segment 33 the pull tab 34 is connected to the release paper near an interior edge 35 of the precut line defining the segment and the width of the pull tab at the line of attachment to the release paper is substantially the same as the width of the release paper segment at the point of attachment. By pulling any one of these pull tabs in a direction perpendicular to the edge to which they are attached (according the arrows 36, 37, 38 and 39), the everting action is initiated without any twisting required by the patient.

Figure 8 illustrates the release paper applied to a self adhesive hydrogel or hydrocolloid wound dressing such as the DuoDerm™ wound dressing assembly 41. The release paper 42 covers substantially all of the adhesive undersurface 43 of the wound dressing 44, and has no substantial opening or aperture near the center (as the wound dressing is designed to cover the entire wound site). The pre-cut or pre-scored line 45 may extend partially or entirely across the release paper. The pull tabs 46 and 47 extend from the outer edge of the release paper in the illustration of Figure 8, but may also be connected to any interior edge of the release paper corresponding to the cut line, or it may fold under the release paper and extend from one edge of the release paper, extend under the release paper, and extend out from under the release paper on the opposite side of the wound dressing and

release paper assembly. In use, the wound paper is placed on the skin 48 over a wound 49, and the release paper is pulled out from under the wound dressing. It should be appreciated that the potential for misplacement of the dressing is
5 minimized with the flexible release paper and the method of applying it which is enabled by the flexible release paper.

The release cloth is made of a sheer woven polyester with a typical weight of 10-100 mg/square inch, and preferably of about 35 mg./square inch. To make a single release cloth, the
10 following method may be used: The cloth is cut to size with a hot knife (which automatically sears the edges to prevent fraying) to the desired shape and laid flat on a piece of plastic film. For each square inch of cloth to be siliconized, prepare silicone by thinning about 60 mg.
15 silicone IS-808 RTV with 68 mg. of mineral spirits or other thinner. Mix well and brush liquid liberally over cloth. Pat off excess liquid between two pieces of paper and hang to dry for 8 hrs. When the silicone brushed cloth is dry, it is ready for use as release paper for the adhesive disk. The
20 process and proportions may be modified for mass production in any desired manner.

The release paper can be made of any lightweight, flexible, tear resistant material which only lightly sticks to the adhesive pad. The release paper should have enough
25 adhesion to remain in place on the adhesive pad during storage and handling, but should also be of limited adhesion so that it can be easily peeled off the adhesive pad during placement. The silicone impregnated material described above has proven very effective and easy to use with commercially available
30 adhesive wafers containing a suspension of polyisobutylene, gelatin and pectin, and with my own skin barrier comprising adhesive tape over a compound of carboxymethylcellulose and polyisobutylene (as more fully described in my co-pending U.S.

Patent Application 09/087,601, filed May 29, 1998 and incorporated herein by reference). Since the material must fold back on itself while maintaining a low profile, it is desired that the fold radius be minimum (typically less than 5 1mm), as demonstrated, for example, in a lightweight polyester fabric (a typical paper backing would be unsuitable). The material could be cloth (woven or unwoven), natural or synthetic fiber, or any strong sheer material. Expanded polytetrafluoroethylene (ePTFE) may also be used in very thin 10 sheets. While the stiff paper used currently in release paper is too stiff for the application, paper might be formulated with suitable flexibility to perform as desired. The applicant knows of no standard measure of flexibility and foldability for fabrics, hence the suitable material must be 15 defined operationally as one that may be peeled from the adhesive pad of the faceplate while the faceplate is held in position on the body. This is an operational definition which readily distinguishes the release paper from the currently available release paper which, if it should be attempted to be 20 held in place during removal would offer significant resistance to folding and force the adhesive pad away from the body while peeling out from under the adhesive pad.

The release cloth could be shaped in a variety of configurations, depending upon the particular application. It 25 could be one continuous strip (shaped like a closed "C") that peels away from the perimeter in one motion. It could be two or more separate strips that peel out one at a time, each having an accessible starter tab. Minimizing the number of strips simplifies the whole process, but regardless of the 30 number of pieces, each strip performs in the unique manner of a low profile peeling as described above. While the inventions have been described in relation to an ostomy faceplate and wound dressings, they may readily be applied to other adhesive appliances used on the body. The release paper

can be segmented as desired, and the pull tabs can be located wherever it is most convenient for the patient or nurse who applies the device. It is expected that material suitable for use in the release paper shall be discovered and applied to
5 the inventions.

Thus, while the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. Other embodiments and
10 configurations may be devised without departing from the spirit of the inventions and the scope of the appended claims.

I claim:

1. A release paper for use with an adhesive pad, said release paper being approximately the same size and shape as the adhesive pad, said size and shape defining an exterior
5 border, said release paper comprising:

a sheet of fabric of approximately the same size as the adhesive pad

said sheet of fabric being impregnated with a tack-resistant material.
- 10 2. The release paper of claim 1 further comprising;

tabs extending from the release paper, said tabs extending beyond the size of the adhesive pad.
3. The release paper of claim 2 further comprising;

at least one precut line in the release paper, said
15 precut line extending inwardly into the release paper from the exterior border.
4. The release paper of claim 3 further comprising;

at least one hole in the release paper.
5. The release paper of claim 3 wherein;

20 the tabs are attached to the release paper at a point inside the exterior borders of the release paper.
6. The release paper of claim 5 wherein;

the tabs are attached to the release paper at a point
inside the exterior borders of the release paper and
25 near one of said at least one precut lines.

7. An ostomy face plate comprising;
- an adhesive pad for adhesive attachment to the body, said adhesive pad having a superficial surface intended to face outwardly from the body, and an anterior surface intended to face the body and adhere to the body, said anterior surface comprising an adhesive substance
- an ostomy pouch coupling ring attached to the superficial surface of the adhesive pad;
- a release paper covering the anterior surface of the adhesive pad, said release paper having a superior surface in contact with the anterior surface of the adhesive pad, and an anterior surface facing the body during placement of the device; and
- said release paper comprising a flexible material which may easily fold, which resists adhesion to the adhesive pad, and which is flexible to the degree that it may be peeled from the adhesive pad while the anterior surface of adhesive pad is held against the body.
8. The ostomy face plate of claim 7 further comprising:
- at least one pull tab attached to the release paper and extending beyond the border of the ostomy faceplate.
9. The ostomy face plate of claim 7 wherein the release paper further comprises a sheet of flexible fabric impregnated with silicone.
10. The ostomy face plate of claim 7 wherein the release paper further comprises a sheet of flexible fabric impregnated with tack resistant material.
11. The ostomy face plate of claim 8 wherein said at least one pull tab is secured to the release paper at a point inside

the border of the release paper, and said pull tab runs outwardly from the release paper on the side of the release paper that is not in contact with the adhesive pad.

12. A method for applying an ostomy faceplate to the body,
5 said method comprising:

providing an ostomy faceplate with an adhesive wafer having an anterior surface comprising an adhesive substance;

providing a release paper to protect the adhesive wafer during storage and handling;

- 10 placing the ostomy faceplate, adhesive wafer and release paper against the body in the desired site of application; and

peeling the release paper from the adhesive wafer while holding the ostomy faceplate in place on the body.

13. A method for applying an adhesive appliance to the body,
15 said method comprising:

providing said appliance with an anterior surface comprising an adhesive substance;

providing a release paper to protect the adhesive substance during storage and handling;

- 20 placing the anterior surface of the appliance against the body in the desired site of application; and

peeling the release paper from the adhesive anterior surface while holding the appliance in place on the body.

1/4

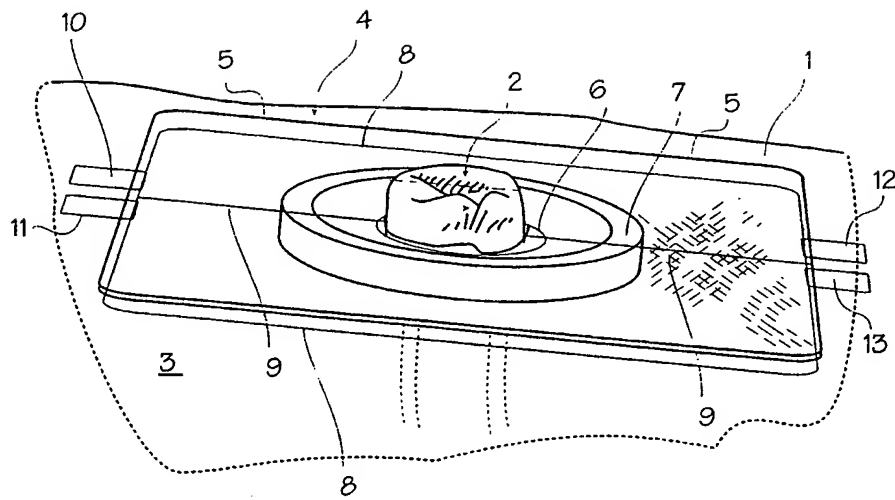


Fig. 1

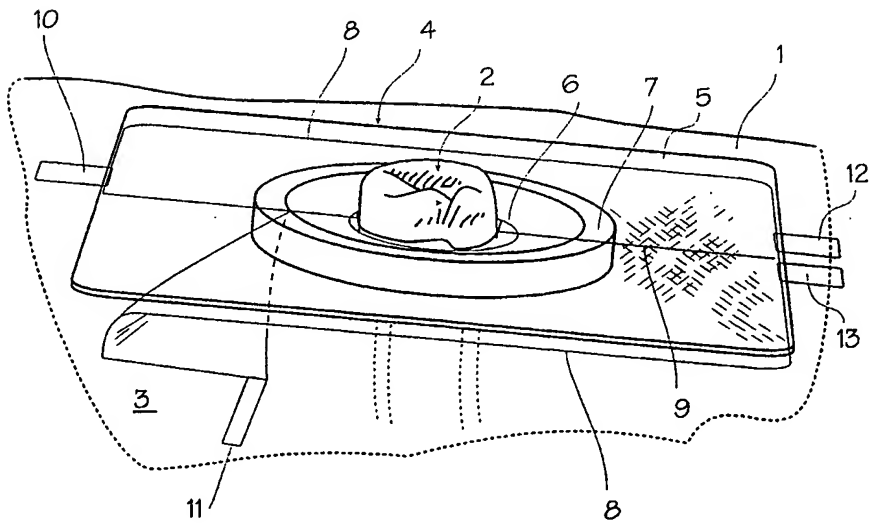


Fig. 2

2/4

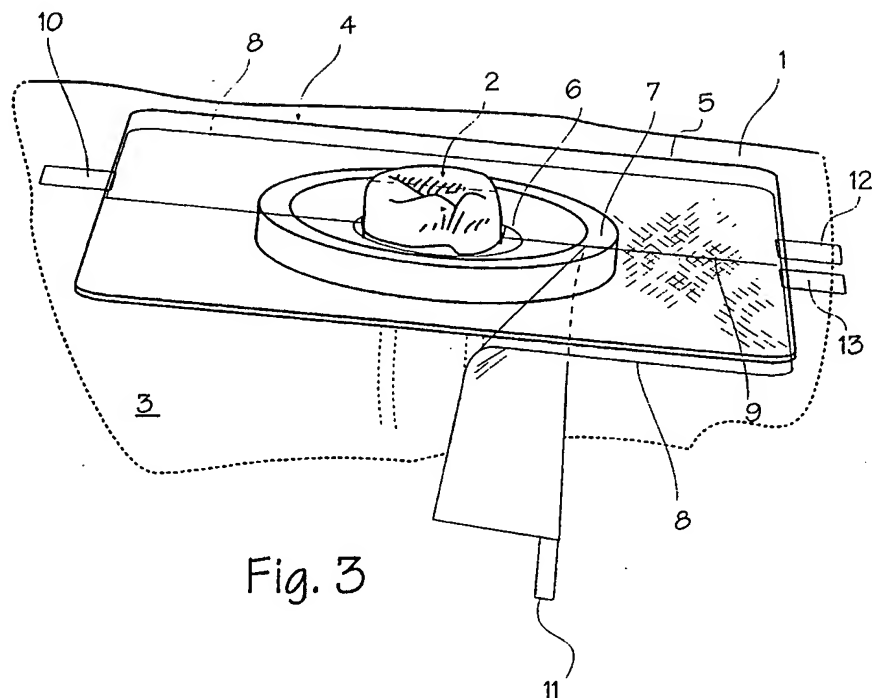


Fig. 3

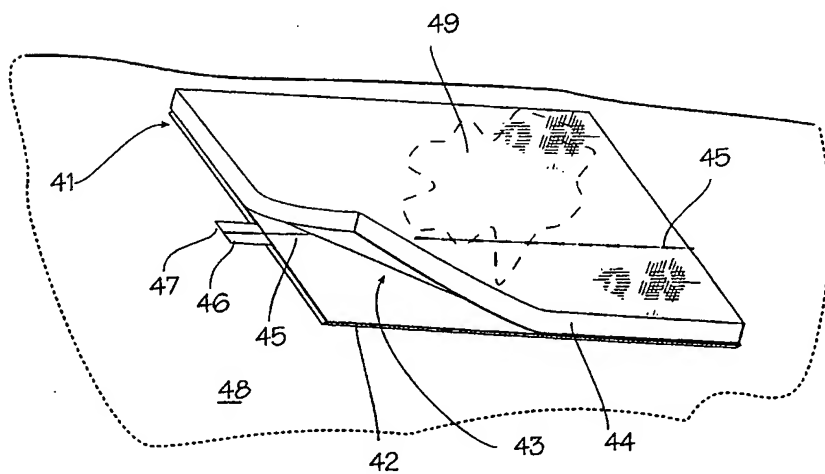


Fig. 8

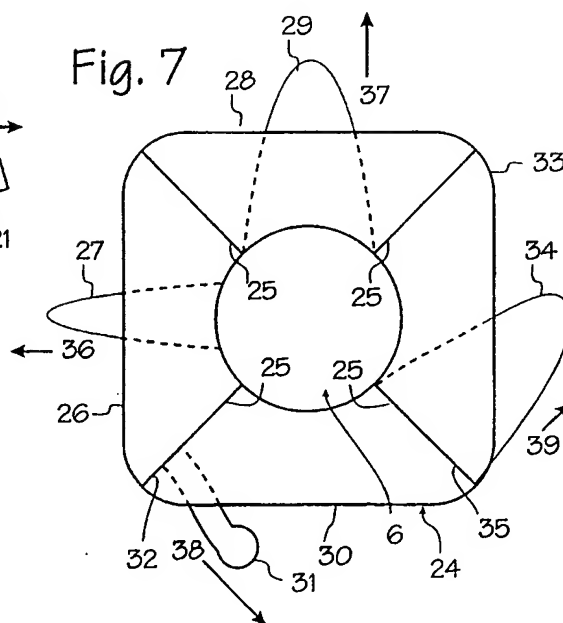
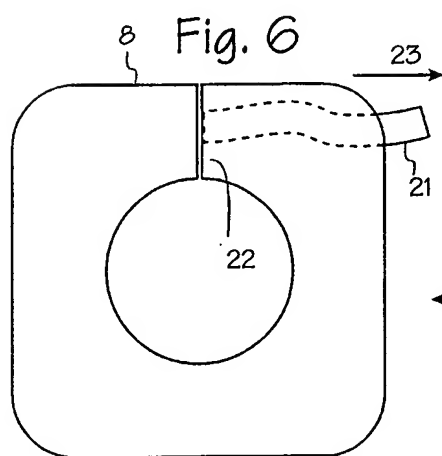
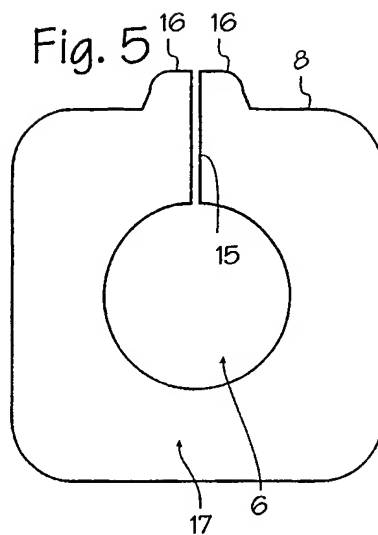
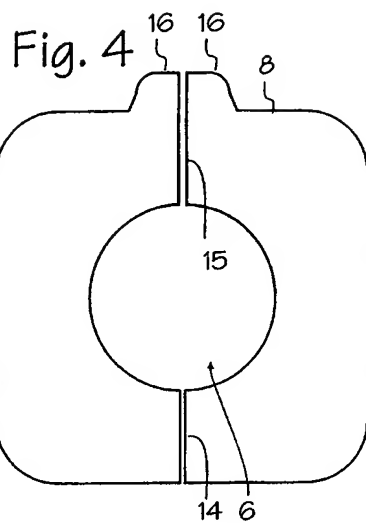
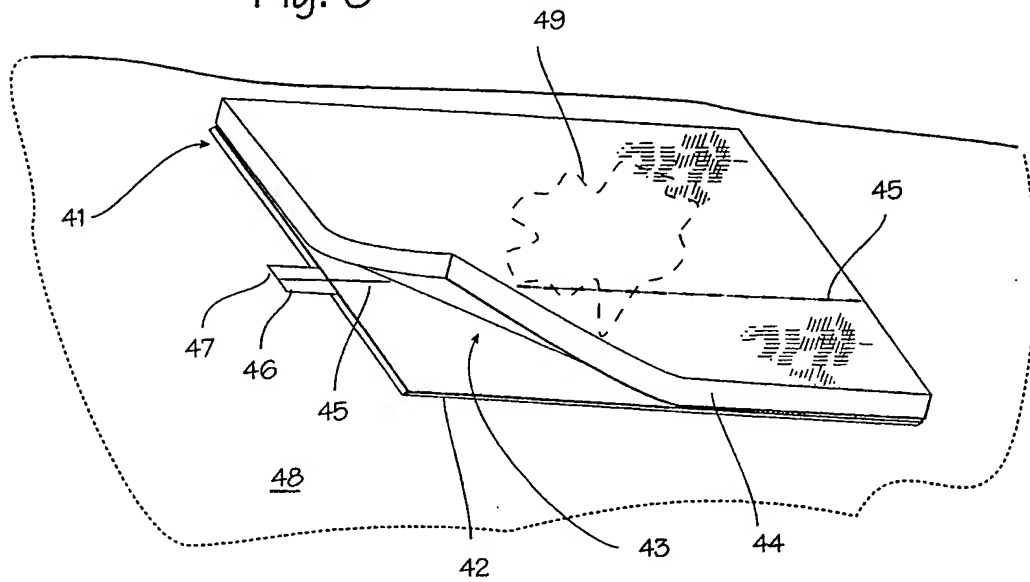


Fig. 9



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/02556

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) :A61F 13/00 US CL :602/57 According to International Patent Classification (IPC) or to both national classification and IPC														
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 602/57 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)														
C. DOCUMENTS CONSIDERED TO BE RELEVANT														
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.												
X	US 5,000,748 A (FENTON) 19 March 1991, entire document.	1, 7, 12, 13												
Y	US 5,112,423 A (LIEBE, JR.) 12 May 1992, entire document.	9, 10												
Y	US 5,709,651 A (WARD) 20 January 1998, entire document.	2-6, 8, 11												
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.														
<table border="0"><tr><td>* Special categories of cited documents:</td><td>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td></tr><tr><td>*A* document defining the general state of the art which is not considered to be of particular relevance</td><td>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td></tr><tr><td>*E* earlier document published on or after the international filing date</td><td>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td></tr><tr><td>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td><td>*Z* document member of the same patent family</td></tr><tr><td>*O* document referring to an oral disclosure, use, exhibition or other means</td><td></td></tr><tr><td>*P* document published prior to the international filing date but later than the priority date claimed</td><td></td></tr></table>			* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family	*O* document referring to an oral disclosure, use, exhibition or other means		*P* document published prior to the international filing date but later than the priority date claimed	
* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention													
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone													
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art													
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family													
O document referring to an oral disclosure, use, exhibition or other means														
P document published prior to the international filing date but later than the priority date claimed														
Date of the actual completion of the international search 21 MARCH 2000		Date of mailing of the international search report 26 APR 2000												
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer KIM M. LEE Telephone No. (703) 308-1191												